2008-04-01
Volume 2, Issue 2

Bloody Good News

Newfoundland and Labrador Provincial Blood Coordinating Program

Special Interest Articles:

- Role of Laboratory Technologists in Transfusion Medicine
- Regulatory Framework – What does it mean to you?

Individual Highlights:

Provincial Program Scope Expands

As the 2007-2008 year ends, we are pleased with the direction the Program has taken over the last twelve months. The scope of the program has broadened to include the formation of a Transfusion Medicine Advisory Group (TMAG) who mandate is to provide medical support and advice to the Program. The TAMG group is represented by Dr. Christo Taylor for Western Region, Dr Kweku Dankwa in the Labrador Grenfell Region, Dr. Barry Gallagher for Central Region and Dr. Lucinda Whitman for Eastern Region and Dr. Karl Misik representing Canadian Blood Services.

We were also fortunate to have our first face-to-face Transfusion Safety Officer (TSO) meeting. The TSO's for the province are Barb Chaulk for Western region, Peggy Sheppard and Clyde Downton for Central Region, Curtis Martin, Donna Sutton and Gail Sharpe for Eastern region. At this point, a representative for the Labrador Grenfell region has not been filled.

The initiatives of both groups include the development of: a) an Informed Consent Policy for the Administration of Blood Products, b) development of a Notification of Transfusion Policy, c) development of a blood product contingency plan, as well as revision of the current guidelines. A meeting with the Newfoundland and Labrador Hospital Boards Association offered further support to the Program in the various initiatives. The year ahead is full of excitement as we continue to provide direction to the Transfusion community within the province.

Regulatory Framework – What does it mean to you?

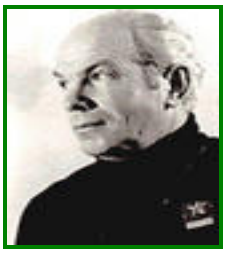
Health Canada through The Food and Drugs Act regulates the blood system in Canada since 1989. A regulatory framework consists of laws and regulations that outline the legal requirements to be met. The current regulations are difficult to follow and are basically only applied to the blood system providers. The newly proposed framework will provide uniform safety standards and regulations, will have the ability to address emerging issues and will involve increased stakeholder participation.

The proposed regulations will address requirements concerning safety, efficacy and quality of blood and blood components through the CSA Standards. The impact on blood establishments will vary based on several factors including management responsibilities, quality systems, standard operating procedures, document control, validation and training.

The steps in the regulatory process include public consultations, draft regulations, preparing an impact statement, consideration of the Special Committee of Council (SCC), pre-publication of the proposed regulations, a comment period, comment analysis, final consideration of the SCC, approval and registration and publication of the final regulations. For more information on Regulatory framework visit: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/brgtherap/blood_infokit_sang_trousse_info_e.pdf

Stakeholder consultations were held and the report was released in Nov. 2007.

Buffy Coat Production Method – Impacts for TMS



Do you know the Canadian pioneer credited with the first mobile blood transfusion service?

Canadian Blood Services will launch the Buffy Coat Production method in Newfoundland in August 2008. The collection bags used by this method will affect transfusion staff throughout all hospitals where blood products are transfused. The largest impact involves the spiking procedure used when inserting a transfusion set into the port of the blood component. This will also impact vendor contracts within the province. In order to ensure a smooth transition to these new blood bags, a Provincial Buffy Coat working group has been created to meet the needs of stakeholders throughout the province. CBS will ensure that in-service sessions will be provided to all end user groups prior to implementation. Information sheets have been posted on the program website to ensure that information is easily accessible. Samples of the blood bags will be available to all hospitals within the province in order to conduct practice sessions. It is important that physicians and nurses who administer blood products be well informed of the new procedures and the impacts regarding availability of certain products such as pediatric size products and single donor platelets versus apheresis platelets. Hospitals that currently pool blood products such as cryo will also be impacted. Videos and posters are available that demonstrate the spiking procedure. A revised Circular of Information for Buffy Coat has also been provided by CBS. During the transition period there will be inventories of the current blood bags as well as the buffy coat bags, therefore staff should be familiar with both products. For more information, visit our website.

Recombinant Factor FVIIa (rFVIIa) - NiaStase®

Did you know the Patient Notification System notifies registered participants within 24 hours of a plasma-derived or recombinant product withdrawal or recall? For more info visit: www.patientnotificationsystem.org

Human factor VIIa, an integral component of hemostasis, is genetically engineered to produce a DNA recombinant product, Recombinant Factor VIIa (rFVIIa). This drug interacts with tissue factor to stimulate the production of thrombin, and with activated platelets, forms a stable clot at the injury site to stop bleeding. Marketed in Canada as NiaStase®, Recombinant Factor VIIa was licensed by Health Canada in 1999 for treatment of bleeding episodes in patients with Hemophilia A or B with inhibitors to factors VIII and IX. An increase in utilization of NiaStase® for treatment of non-hemophilic bleeding has been noted. Surgical and trauma patients are treated with NiaStase® to control massive bleeding, thus reducing mortality rates. By reducing the size of hematomas in patients with intercerebral hemorrhage, treatment with NiaStase® has prevented greater neurological damage. Patients experiencing GI bleeding, post-partum hemorrhage or bleeding due to advanced liver disease have also been treated successfully with NiaStase®. Clinical trials report that rFVIIa has the potential to be an effective treatment in hemostatically unstable patients. Use of rFVIIa is not without risk; patients with coronary artery disease, crush injury, septicemia and DIC are susceptible to thromboembolic events. There is an increasing interest by physicians regarding rFVIIa use in other clinical conditions. NiaStase® is an extremely expensive product. Ensuring costs are contained would be best managed by having guidelines for rFVIIa use in various clinical conditions. Canadian utilization guidelines for rFVIIa use in hemophilia are available; however, none exists for non-hemophilic use. The National Advisory Committee is developing a framework for guidelines. Further studies may determine if the use of NiaStase® would help conserve the supply of blood and blood products.

The Laboratory Technologists Role in Transfusion Medicine

At the heart of the Transfusion Medicine profession is the Laboratory Technologist's expertise in the transfusion process. The technologist ensures national standards and provincial policies are upheld to provide the recipient with the safest product available. The laboratory technologist is responsible for inventory management and product distribution of blood components and blood products. The technologist performs the required compatibility testing necessary to ensure the patient receives the safest product available. In many instances, specialized testing is required to identify blood group antibodies that could negatively affect the patient's health if these antibodies were not recognized. The technologist may also be required to prepare specialized products such as washed red blood cells for specific patient needs. Education is a critical component of the technologist's role in transfusion. Professional development and educational in-service sessions provide the technologist the opportunity to share acceptable transfusion practices and information related to specific products with other healthcare professionals while maintaining competency in transfusion practices. As a key member of the Transfusion Committee, the technologist provides input into the development of transfusion policies for medical and nursing staff. Recognition of the signs and symptoms of adverse transfusion events, the investigation and reporting of such events is critical in ensuring a high caliber of patient care. Technologists also monitor, track and trend changes in transfusion practice and product utilization and report these findings to the Laboratory Manager.

The Blood Bank Technologist

Quality Systems - Accreditation

Medical laboratories are responsible for the testing of biological samples with the purpose of assisting in the diagnosis and treatment of diseases. Laboratories demonstrate compliance with standards through a process of accreditation. In order to accomplish this, one must understand the difference between certification and accreditation, the difference between policy, process and procedure as well as have a good understanding of a quality system.

Certification is defined as a "procedure by which a third party gives written assurance that a product, process or services conforms to specified requirements". ***Accreditation*** is defined as a ''procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks" (ISO/IEC Guide 2). The accreditation process is performed by a third party organization. This does not include peers, suppliers or customers. The third party is independent of the laboratory or the parent organization. In preparing for accreditation a Steering Group should be established to prepare a gap analysis, develop a global policy, select a Quality Manager and develop a quality manual.

For more information on Quality Systems and Accreditation, the AABB has several publications specific to Quality.

"Quality is never an accident; it is always the result of intelligent effort".

John Ruskin

English critic, essayist, & reformer (1819 – 1900)

Transfusion Associated Circulatory Overload (TACO)

Transfusion Associated Circulatory Overload TACO) is an under recognized and under reported adverse reaction to transfusion. Occurring in approximately 1 in 700 transfusions, TACO is due to the excess volume or the rapid administration of product and the inability of the recipient's cardio-vascular system to cope. Certain populations of patients, including infants, the elderly, patients with cardiac, pulmonary or renal failure and those with chronic anemia are at a higher risk for fluid overload. TACO may present quite quickly and dramatically, during or within hours of trans-fusion. Recipients may experience congestive heart failure accompanied by all or any of the following: dyspnea, orthopnea, tachycardia, elevated blood pressure, productive cough with pink, frothy sputum. Treatment of TACO involves discontinuation of the transfusion as soon as symptoms appear. The patient should be elevated to a sitting position, supplementary oxygen and diuretics administered and appropriate cardiac support given. TACO may be prevented in susceptible patients by slowing the rate of infusion, transfusing smaller volumes and pre-medicating with a diuretic. Particular attention should be given to patients with chronic anaemia who usually have a normal blood volume prior to transfusion. Certain patients receiving transfusions of albumin who are unable to cope with a large increase in blood volume over a short period of time should also be monitored for signs and symptoms of TACO. All cases of TACO should be reported to the PBCP and Health Canada.

Answers from Issue 2

This son of a tobacco merchant became a famous protein scientist:
Dr. Edwin Cohn

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http://www.health.gov.nl.ca/health/bloodprogram/index.htm

TACO (cont'd)

Case Study #3

A 67 year old male admitted with a bowel obstruction. The patient had been transfused within the last 3 months but was not immuno-compromised. He was not pre-medicated nor transfused under anesthesia. The patient's blood group was A Positive. The patient was transfused 3units FFP from 1620 hrs to 1800 hrs at which time he developed urticaria and swelling to the eyes. The patient's symptoms subsided when treated with antihistamine. The adverse event was reported to PBCP but not to the blood supplier.

1. Classify type of reaction

2. What was the relationship of the adverse event to the transfusion?

3. What was the severity of the reaction?

4. What was the outcome of the adverse event?

Case Study #2 Interpretation

1. *Febrile non- hemolytic transfusion reaction*
2. *Relationship of adverse event to transfusion – probable*
2. *Severity of the reaction – Grade 1 (minor)*
3. *Outcome – Minor sequelae*

Each newsletter will contain an interesting case study for you to review. The type of adverse event and answers to the questions will be provided in the next edition of the newsletter.